TFW 1614

TRANSMITTAL LETTER (General - Patent Pending)	Docket No. UMD-0104

In Re Application Of: **Welsh et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/534,296	December 9, 2005	Not yet assigned	46046	1614	5196

Title: **Novel Pharmacophore for The Discovery and Testing of NA, K-ATPase Inhibitor Compositions and Methods for Their Use in Treating Cardiovascular Diseases and Conditions**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Courtesy copy of International Preliminary Report on Patentability
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in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **50-1619** as described below.
  - ☐ Charge the amount of
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Jane Massey Licata

Signature

Dated: **August 9, 2006**

Jane Massey Licata, Reg. No. 32,257

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

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(Date)

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PATENT COOPERATION TREATY

M

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
JANE MASSEY LICATA
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MARLTON, NJ 08053

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	05 MAY 2006
Applicant's or agent's file reference UMD-0063	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US03/35636	07 November 2003 (07.11.2003)	07 November 2002 (07.11.2002)

Applicant

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Young J. Kim Telephone No. (571) 272.1600

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference UMD-0063	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/35636	International filing date *(day/month/year)* 07 November 2003 (07.11.2003)	Priority date *(day/month/year)* 07 November 2002 (07.11.2002)

International Patent Classification (IPC) or national classification and IPC

IPC: G01N 33/48(2006.01)
USPC: 702/19

Applicant

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of — sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07 June 2004 (07.06.2004)	11 April 2006 (11.04.2006)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Young J. Kim Telephone No. (571) 272.1600

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/35636

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-33 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 34-36, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-9, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/35636

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 3 and 4	YES
	Claims 1 and 2	NO
Inventive Step (IS)	Claims 3 and 4	YES
	Claims 1 and 2	NO
Industrial Applicability (IA)	Claims 1-4	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by Halter et al. (Pharmacies, September 1992, Vol. 47, No. 9, Abstract only).

Halter et al discloses a pharmacopoeia model of Na+/K (+)-Atlases (Abstract), anticipating claim 1.
With regard to claim 2, the pharmacopoeia model is employed to describe/generate all corresponding isotropic substrates, which evidences that the pharmacopoeia of Halter et al can be used as a basis for compounds directed to isotropic Na, K-Atlases inhibition (Abstract).

Therefore, Halter et al anticipate the inventions as claimed.

Claims 3-4 meet criteria set out in PCT Article 33(2) and (3), because the prior art does not teach or fairly suggest the claimed invention.

Claims 1-4 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-4 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s):

Claims 1-4 is rejected as being indefinite because the pharmacophore model defined by Table 4 and Table 5 which recites that various spheres which comprises some attributes, but does not recite what defines these spheres as well as the actual structure produced by the spheres, rendering the metes and bounds of the claims indefinite.

Claims 4 recites the phase, "novel pharmaceophore model...wherein X is N, O, S, or C." However, the term, "X" further limits the Na, K-ATPase inhibitor compounds derived from the claimed pharmacophore model and not from the actual pharmacophore model itself.

Claims 3 and 4 are indefinite because the claims are drawn to a product, but within the product claims, a method of use is embedded (the pharmacophore model "produces an Na, K-ATPase inhibitor compound..."). No interpretation can be made for these claims, and therefore, have not been further treated on their merits.

Claims 1-4 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claims are not fully supported by the description. The application, as originally filed, did not describe:

Claims 1-4 are rejected as failing to provide written description for the genus of claims embraced by the claims.
Claim 1 is not limited to any particular pharmacophore of a specific biological molecule, but rather defined by parameters set forth in Tables 4 and 5.

The parameters provided by Table 4 required that the pharmacophore object have a varying number of "spheres" each of which is defined by the type of bonding. Such model would represent a wide array of species of biological molecules for which the instant description clearly lacks. Table 5 discloses what appears to be varying ranges of distances the spheres could have (defined in angstroms). But such description does not sufficiently narrow the claimed pharmacophore so as to allow the instant description to disclose a representative number of species embraced by the claimed genus.
For the above reasons, the claims fail to provide a sufficient written description of the claimed subject matter.